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 INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
 (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PU0265		FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/SE2003/001016	International filing date (day/month/year) 17.06.2003	Priority date (day/month/year) 27.08.2002	
International Patent Classification (IPC) or national classification and IPC C12N 15/10			
Applicant Amersham Biosciences AB et al			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 18.03.2004		Date of completion of this report 5.11.2004	
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Form PCT/IPEA/409 (cover sheet) (January 2004)

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☐ the description:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____ as originally filed/furnished

pages* _____ as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____ as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
- ☒ claims Nos. 11-13 (partially)

because:

- ☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. 11-13 (partially)

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the
Administrative Instructions in that:

- | | | |
|----------------------------|--------------------------|-----------------------------------|
| the written form | <input type="checkbox"/> | has not been furnished |
| | <input type="checkbox"/> | does not comply with the standard |
| the computer readable form | <input type="checkbox"/> | has not been furnished |
| | <input type="checkbox"/> | does not comply with the standard |

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with
the technical requirements provided for in the Annex C-bis of the Administrative Instructions.

- ☐ See Supplemental Box for further details.

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-10, 14-21</u>	YES
	Claims	<u>11-13</u>	NO
Inventive step (IS)	Claims	<u>1-10, 14-21</u>	YES
	Claims	<u>11-13</u>	NO
Industrial applicability (IA)	Claims	<u>1-21</u>	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Documents cited in the International Search Report:

D1: WO 9811140 A1

D2: Journal of Chromatography A, Volume 864, 1999, Josefine Persson et al: "Purification of protein and recycling of polymers in a new aqueous two-phase system using two thermoseparating polymers", pages 31-48

D3: International Symposium on Separations for Biotechnology Reading: Separation for biotechnology 3. Cambridge: royal Society of Chemistry, 1994, Folke Tjerneld et al: "Utilization of Temperature-induced Phase Separation for Purification of Biomolecules", pages 505-511

D4: Biotechnology and Bioengineering, Volume 78, no. 4, 20 May 2002, S.C. Ribiero et al: "Isolation of Plasmid DNA from Cell Lysates by Aqueous Two-Phase Systems", pages 376-384

D1 discloses different composition, among others, a composition comprising Reppal PES 200, a hydroxypropyl starch, and UCON 50-HB-5100, a copolymer of ethylene oxide and propylene oxide with a cloud point of 50°C. Reppal PES 200 is preferably used in a concentration of 1-30 % (w/w) and UCON 50-HB-5100 is preferably used in a concentration of 0.5-30 % (w/w). (Page 10, lines 7-16; page 12, lines 25-28; page 14, lines 18-19; the claims.)

D2-D3 disclose similar compositions comprising a first polymer that exhibits inverse solubility characteristics at temperatures below about 60°C and a second polymer that is immiscible in the first polymer.

D2 discloses a composition comprising EO50PO50 and HM-EOPO and D3 discloses a composition comprising Ucon in combination with dextran. (D2: figure 4; D3: page 506, paragraph 2.)

.../...

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

The present claims 11-13 relate to a composition, such as the one described in D1, for extraction of plasmid DNA. However, the scope of claims 11-13 covers the composition per se, regardless of what it is used for. Consequently, the subject matter claimed in claims 11-13 lacks novelty.

To summaries, the subject matter claimed in claims 11-13 lacks novelty. The subject matter claimed in claims 1-10 and 14-21 is novel and is considered to involve an inventive step. The subject matter claimed in claims 1-21 is considered to be industrially applicable.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 11-13 relate to compositions comprising a first and a second polymer each having particular properties, namely, the first polymer should exhibit inverse solubility characteristics below about 60°C and the second polymer should be immiscible in the first polymer. The claims cover all compositions having such polymers, whereas the description supports only a limited number of compositions. It is considered impossible to compare the parameters of the claims with known compositions. These parameters are considered to render the scope of the claims unclear, see PCT art 5 and 6.

Wordings such as "about" is considered to lead to a lack of clarity. Consequently, the wording of claims 2, 4, 6, 7, 11, 14, 17 and 20 is considered to render the scope of the claims unclear and thus, the claims are considered to not fulfil the requirements of PCT Art 6.